

C. Remarks:

Upon entry of the amendments claims 1-23 will be pending. Claims 4, 12-14, and 16-17 have been amended herein. Support for the amendments can be found throughout the specification and claims as filed.

Claims 22 and 23 are new. Support for these claims can be found at least in claims 4 and 16, respectively, as previously presented.

Accordingly, no new matter has been added.

Indefiniteness

The Examiner rejects claims 4, 12-14, and 17 under 35 U.S.C. § 112, ¶ 2 for failing to particularly point out and distinctly claim the subject matter of the claimed invention. Applicants traverse the rejection as applied to the claims presented herewith.

Claim 4 has been amended herein to delete recitation of the narrower range limitation: “preferably between 20°C and 60°C.” The narrower range limitation is now recited by new claim 22. Applicants submit that the amendment to claim 4 overcomes the rejection and request it be withdrawn.

Although the Examiner did not reject claim 16, Applicants have applied the same logic to this claim and have amended claim 16 to delete recitation of the narrower range limitation: “preferably between 0.3% and 3%.” The narrower range limitation is now recited by new claim 23.

Claims 12-14 have been amended herein to make clear that the recited methods are intended for *in vivo* use. Applicants submit that one of ordinary skill in the art would understand the language of amended claims 12-14 as such when read in view of the specification as filed. Accordingly, Applicants assert that the rejection should be withdrawn.

Finally, claim 17 has also been amended herein to correct a typographical error. As amended, claim 17 properly recites “the complexion” as it refers to something possessed by “an individual.” Applicants respectfully request that the rejection be withdrawn.

Novelty

The Examiner rejects claims 1-11 and 15 under 35 U.S.C. § 102 (b) as anticipated by U.S. Patent No. 5,874,401 (“Sanou”). According to the Examiner, the pollen extract disclosed by Sanou reads on the extract as presently claimed. (*See* Office Action at page 4). Applicants disagree as the rejection is applied to the claims as presented herewith.

The extract as currently claimed in claim 1 is an extract of buds of *Cryptomeria japonica* *D. dons*. The extract is obtained in three steps: (1) a solid/liquid extraction; (2) a solid/liquid separation; and (3) a liquid phase retrieval. As those skilled in the art will appreciate, the term “buds” also ordinarily refers to the rudimentary state of a stem or branch, and not only to an unexpanded flower, as suggested by the Examiner (*see* Office Action at page 4). The process of extraction of the present invention is conducted directly on stem buds rather than flower buds. That Applicants’ invention concerns the use stem buds rather than flower buds is further evidenced by the use of the term “Bourgeons” throughout the corresponding PCT application (Publication No. WO2004/075820). In the French language, “flower buds” is designated by the

term “bouton floral,” whereas the French term “bourgeon” more generally denotes “buds” of the tree or plant. Courtesy copies of relevant pages from a French-English dictionary are provided herewith for the Examiner’s convenience and in support of the definitions presented above.

In contrast, Sanou discloses a specific protein prepared from *Cryptomeria japonica* pollen as a desensitization agent. The cedar pollen is collected from a male flower, which is suspended and extracted in aqueous solution. This extraction is followed by centrifugation, with the resultant supernatant mixed with “CETAVLON” and again centrifuged. The resultant sediment is then dialyzed, filtered, and fed to a column where it is washed in several steps in order to elute a specific protein fraction. (See Sanou at col. 3, line 10 through col. 4, line 5; and Example A-1 and A-2, cols. 13 and 14). Sanou does not teach or suggest a *Cryptomeria japonica* extract derived from stem buds.

As the claimed extract is prepared from stem buds, Sanou cannot be said to teach each and every element of the claimed invention. Accordingly, Sanou does not anticipate claim 1. Similarly, claims 2-11 and 15, which depend directly or indirectly from claim 1 and incorporate all of the limitations of claim 1, are not anticipated by Sanou. Thus, the rejection of claims 1-11 and 15 should be withdrawn.

Obviousness

Claims 1-11 and 15 are alternatively rejected under 35 U.S.C. § 103(a) for being obvious in view of Sanou. According to the Examiner, even if the claimed extract is not identical to that disclosed by Sanou, the differences between the two are so slight that the extract disclosed by Sanou is “likely to inherently possess the same characteristics of the claimed extract.”

Therefore, the Examiner concludes that the claimed extract would have been *prima facie* obvious in view of Sanou. (See Office Action at page 4). Applicants traverse.

A rejection based on 35 USC § 103 cannot be predicated on the mere identification of individual components of the claimed invention in the prior art. Rather, in order for an obviousness rejection to be proper, there must be a teaching or suggestion within the prior art that motivates the ordinarily skilled artisan, having no knowledge of the claimed invention, to modify the teachings of the prior art with a reasonable expectation of success in achieving the claimed invention. Applicant respectfully asserts that this burden has not been met.

First, one of ordinary skill in the art would not have been motivated to modify Sanou in a manner required to meet the invention as recited by the present claims. The problem with which Sanou is concerned relates to treating, preventing, and diagnosing allergic reactions to the pollen of *Cryptomeria japonica* D. dons. For this reason, the *Cryptomeria japonica* D. dons extract disclosed by Sanou is specifically derived from pollen (*i.e.*, the male flower) in order to isolate a proteinaceous component for use as a desensitizing agent, which when administered over time will lessen or prevent allergic reactions. Sanou is silent with regard to utilizing stem buds (or any other part) of *Cryptomeria japonica* D. dons to achieve the pollen-based desensitizing agent disclosed therein. Accordingly, one of skill in the art at the time of invention, upon reading Sanou, would have been discouraged from following the path that was taken by Applicant in arriving at the claimed invention.

Moreover, one of ordinary skill in the art would conclude that modifying Sanou in the manner suggested by the Examiner to achieve the claimed invention would render Sanou unsatisfactory for its intended purpose, *i.e.*, isolating a cedar pollen protein for treating, preventing, and diagnosing allergic reactions to the pollen of *Cryptomeria japonica* D. dons.

This rebuts the Examiner's assertion that the extract disclosed by Sanou is "likely to inherently possess the same characteristics of the claimed extract," because the claimed extract is not derived from the pollen-bearing male flower. Obviousness cannot be established via inherency on a mere likelihood. Rather, a basis in fact and/or technical reasoning must be established to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. (*See Ex parte Levy*, 17 USPQ 2d 1461, 1464 (BPAI 1990)).

For all of the foregoing reasons, Applicants assert that the Examiner's reliance on Sanou to establish obviousness is improper. Accordingly, the rejection of claims 1-11 and 15 as obvious in view of Sanou should be withdrawn.

Claims 1-21 are also rejected under 35 U.S.C. § 103(a) for being obvious in view of Sanou in combination with U.S. Patent 5,073,628 ("Matsuhashi"). According to the Examiner, one of ordinary skill in the art at the time of invention would have been motivated to combine the teachings of Sanou and Matsuhashi to achieve claims 1-21. The Examiner concludes that based on the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention, and that the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention. (*See Office Action* at pp. 5-6). Applicants traverse the rejection as applied to claims 1-23 presented herewith.

Applicants reiterate the arguments provided above for overcoming Sanou but do not repeat them here.

Matsuhashi does not cure the deficiencies of Sanou. In fact, Matsuhashi suffers from similar deficiencies as Sanou. Specifically, the problem addressed by Matsuhashi also relates to treating, preventing, and diagnosing allergic reactions to the pollen of *Cryptomeria japonica D. dons* by inducing production of immunoglobulin G and M antibodies. (*Compare Matsuhashi Abstract with Sanou Abstract*). For this reason, the *Cryptomeria japonica D. dons* extract disclosed by Matsuhashi is also specifically derived from pollen (*i.e.*, the male flower) in order to isolate a proteinaceous component for use as a desensitizing/hyposensitizing agent, which when administered over time will lessen or prevent allergic reactions. (See Matsuhashi col. 4, line 50 through col. 5, line 41; Example 1; and col. 13, lines 16-46). Like Sanou, Matsuhashi is also silent with regard to utilizing stem buds (or any other part) of *Cryptomeria japonica D. dons* to achieve the pollen-based desensitizing agent disclosed therein.

Accordingly, one of skill in the art at the time of invention, upon reading Matsuhashi in view of Sanou, would have been discouraged from following the path that was taken by Applicant in arriving at the claimed invention. As such, even when the teachings of Sanou and Matsuhashi are combined, the combination still does not provide the invention as recited by claims 1-23 presented herein. Therefore, one of ordinary skill in the art, possessing only the teachings of Sanou either alone or in combination with Matsuhashi, would not have had a reasonable expectation of success at the time of invention to achieve an extract of *Cryptomeria japonica D. dons* derived from stem buds. Applicants therefore contend that claims 1-23 as presented herewith are unobvious in view of Sanou in combination with Matsuhashi, and respectfully request reconsideration and withdrawal of the rejection.

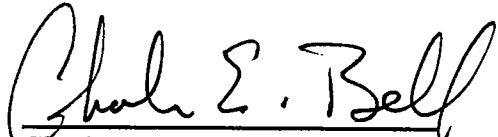
D. Conclusion

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Without an extension of time, this response is due on or before November 10, 2006. The Commissioner is hereby authorized to charge payment of any fees that may be required, or credit any overpayment of same, to Deposit Account No. 08-1935, Reference No. 1759-204.

Respectfully submitted,

Dated: November 9, 2006

A handwritten signature in cursive script that reads "Charles E. Bell". The signature is written in dark ink and is positioned above the printed name and contact information.

Charles E. Bell, Reg. No. 48,128
Attorney for Applicants
c/o Heslin Rothenberg Farley & Mesiti P.C.
Telephone: (518) 452-5600
Facsimile: (518) 452-5579
Customer Number 23405.